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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,077	03/12/2004	Ramachandra Reddy	VASG-P01-001	2078
28120 7590 01/16/2008 ROPES & GRAY LLP PATENT DOCKETING 39/41 ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER CHONG, KIMBERLY	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 01/16/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/800,077	Applicant(s) REDDY ET AL.	
	Examiner Kimberly Chong	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7-11,14,16,18-25,59,61,62 and 65-83 is/are pending in the application.
- 4a) Of the above claim(s) 18-25,61,62 and 65-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,7-11,14,16,59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 10/01/2007 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 05/30/2007 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 10/01/2007, claims 1, 5, 7-11, 14, 16, 18-25, 59, 61-62, and 65-83 are pending, claims 1, 5, 7-11, 14, 16 and 59 are currently under examination, claims 2-4, 6, 12-13, 15, 17, 26-29, 30-58, 60, 63-64 and 84-91 have been canceled and claims 18-25, 61-62, and 65-83 are withdrawn as being drawn to a non-elected invention.

New Claim Objections and Rejections

The following newly applied objections and rejections are necessitated by claim amendments filed 10/01/2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 and 14 depend from canceled claim 3 and therefore are indefinite because it is unclear what further limitations the claims would encompass.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 7-11, 16 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Monia et al. (U.S. Patent Number 6,270,030).

The claims are drawn to an isolated nucleic acid compound comprising a nucleotide sequence of between 20 and 25 nucleotides which is complementary to a

region of an EphB4 transcript, wherein the EphB4 transcript has a nucleotide sequence set forth in SEQ ID NO: 392, wherein the nucleic acid compound comprises one or more modified backbone or base moiety and comprises at least one comprises at least one 2'-O-alkylated ribonucleotide, wherein the compound is single-stranded, a DNA molecule, a RNA molecule or DNA strand and an RNA strand, wherein the compound has at least one internucleotide linkage and drawn to pharmaceutical composition comprising said nucleic acid compound.

Monia et al. teach an antisense compound, 20 nucleobases in length, that is complementary to a region of an EphB4 sequence set forth in SEQ ID NO: 392 (see attached sequence alignment and SEQ ID NO: 41, column 75). Monia et al. teach the compound is a DNA molecule or a RNA molecule (see column 5, lines 35-50), wherein the compound comprises one modified backbone or base moieties, wherein the compound has at least one internucleotide linkage and wherein the compound comprises at least one 2'-O-alkylated ribonucleotide (see columns 6-8). Monia et al. further teach chimera compounds comprising RNA and DNA (see columns 9-10). Monia et al. teach compositions comprising said nucleic acid compounds and pharmaceutically acceptable carriers (see columns 11-12). The instant specification does not define the degree with which the antisense compound is complementary to the EphB4 sequence and therefore the limitation in the claim reciting a "nucleic acid compound comprising a nucleotide sequence of between 20 and 35 nucleotides which is complementary to a region of an EphB4 transcript sequence" is interpreted to mean the nucleic acid compound does not necessarily need to be 100% complementary to the

target sequence. The claims are given their broadest reasonable interpretation and one of skill in the art would understand that an antisense compound does not need to be 100% complementary to a target gene to be able to recognize and bind to a specific sequence. As disclosed by Monia et al., it is understood by one of skill in the art that a compound need not be 100% complementary to hybridize to a target sequence and complementary means the antisense compound has a sufficient degree of corresponding positions that are capable of base pairing to a target sequence (see column 5, lines 1-25).

Monia et al. do not teach the antisense compound decreases expression of EphB4 in a cell, however the nucleic acid sequence taught by Monia et al. meets the structural limitation of claims 1, 7-11, 16 and 59 of the instant application and would be expected to hybridize to a nucleic acid encoding of EphB4 and decrease expression of EphB4 in a cell. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property. The claiming of an unknown property which is inherently present in the prior art does not necessarily make the claim patentable. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference. . *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Furthermore, "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)."

Thus, the instant claims are anticipated by Monia et al.

Response to Applicant's Arguments

Re: Claim Objections

The objection of claim 14 as reciting non-elected subject matter is obviated in response to claim amendments filed 10/01/2007.

Re: Claim Rejections - 35 USC § 102 or 35 USC § 103

The rejection of claims 1, 3, 5-7, 9-11, 13, 16 and 59 under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) as being anticipated by or obvious over Bennett et al. in the Office action mailed 05/30/2007 is withdrawn in response to claim amendments filed 10/01/2007.

The rejection of claims 1, 3, 5-8, 10-11, 13, 16 and 59 under 35 U.S.C. 102(e) or 35 U.S.C. 103(a) as being anticipated by or obvious over Khvorova et al. in the Office action mailed 05/30/2007 is withdrawn in response to claim amendments filed 10/01/2007.

Re: Claim Rejections - 35 USC § 103

The rejection of claims 1, 3, 5-8, 10-11, 13-14, 16 and 59 under 35 U.S.C. 103(a) as being unpatentable over Miyagishi et al. (Oligonucleotides 2003, Vol. 13: 325-333),

Promega (siRNA Designer Version 1.1, May 2003, www.promega.com), and Khvorova et al. is withdrawn in response Applicant's arguments filed 10/01/2007.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

KC
Examiner
Art Unit 1635

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